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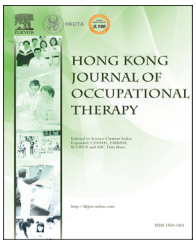

ORIGINAL ARTICLE

Are "Smart Pressure Monitored Suits" "Smarter" than Conventional Garments in Clinical Applications?☆

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Summary *Objective/Background:* There is still no standardized regime to prescribe pressure garments with quantifiable pressure dosage to patients with different medical conditions. This study aimed to examine the efficacy of a newly developed system [a smart pressure monitored suit (SPMS)] for pressure intervention when compared with the conventional method of pressure garment production (conventional garment or CG). The SPMS is designed with a set of standard methods of measurements and computerized pattern drafting software (YUKA) to adjust the pressure range through computation of the percentage of strain directly on the drafted pattern. The CG was fabricated by occupational therapists in clinical settings.
Methods: A selected group of patients who required pressure therapy intervention was recruited through convenience sampling. They were provided with both a SPMS and a CG, each to be worn for 1 month. The interface pressure levels of both garments were measured before the implementation. Patients' feedback was collected using a standardized questionnaire on the comfort of wear, elasticity, and durability of the garments.
Results: There was a significant difference in the deterioration of pressure between the SPMSs and the CGs ($p < .05$) before and after 1 month of wear. The satisfaction on overall efficacy of the SPMSs was significantly higher than that of CGs ($p < .05$).

☆ Conflicts of interest: All contributing authors declare no conflicts of interest.

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Conclusion: This standardized system using a SPMS appeared to provide a more accurate and consistent pressure range and long-lasting effect to the patients. It also appeared to be more efficient and effective in terms of production and fabrication.

Introduction

Pressure therapy usually prescribes the use of pressure garments for the management of postburn hypertrophic scars, varicose veins, and lymphoedema (Bradley, 2001; Korpan, Crevenna, & Fialka-Moser, 2011; Ripper, Renneberg, Landmann, Weigel, & Germann, 2009). Pressure garments can be made in-house by occupational therapists in the hospital or burns units. They can also be ordered through commercial companies (Macintyre & Baird, 2006). These elastic garments can either be tailor-made based on individual's body dimension measurements and specific requirements, or be purchased at different fixed sizes already produced commercially. The pattern design for garment fabrication and the fitting of pressure garments mainly depend on the experiences of the therapists or in some cases, by nurses or other allied health workers. The interface pressure produced by these pressure garments was seldom measured and monitored in clinical situations (Lai & Li-Tsang, 2009; Macintyre, 2007; Macintyre & Baird, 2006; Mann, Yeong, Moore, Colescott, & Engrav, 1997). Therefore, whether these garments are therapeutically effective is a question that is yet to be answered. Until recently, there was still no standardized regime to prescribe pressure garments with a quantifiable pressure dosage to patients with different medical conditions.

In light of the aforementioned drawbacks, a smart pressure monitored suit (SPMS) (Fig. 1) was invented by Li's research team, aiming to standardize the therapeutic intervention of pressure therapy through a self-developed computerized YUKA system (Li-Tsang, 2009). The YUKA software was developed to generate patterns with different percentage of strain based on the individual's body dimensions. After measuring the body dimensions, therapists can simply input the data and the desirable pressure range into the YUKA system. The garment pattern will be automatically drafted for each patient based on the pressure range needed to control the medical condition. The production of the pressure garment will become more effective and efficient. A standard fabric, which had its durability, elasticity, and permeability already tested, was adopted in the fabrication of the SPMS to increase wearing comfort. To test the end result of pressure ranges generated by the SPMS, the Pliance X system, which is a valid pressure monitoring machine, was used to measure and monitor the interface pressure (Lai & Li-Tsang, 2009).

To prove the effectiveness of this new method of producing pressure garments, a clinical comparative study was conducted. The aim of this study was to examine the efficacy of the SPMS for pressure intervention when compared with the conventional method of production. A group of patients who required pressure therapy intervention was selected to participate in the study using the method of convenient sampling. They were provided with both the SPMS and conventional garments (CGs), each to be worn for 1 month. The interface pressure values of both types of garments were measured before the implementation of the pressure intervention. Patients' feedback was collected regarding the wearing comfort, elasticity, and durability of the garments.

Materials and methods

Study design

An experimental pretest—post-test design was used in this study. Recruited participants were randomly assigned into two groups. One group of the participants was given the CG for 1 month followed by prescription of the SPMS for the next month, while the second group was given the SPMS for 1 month and then the CG for the next month. All participants were asked to fill in a questionnaire at the end of 2 months after they finished wearing both garments. They were blind to the type of garment they were prescribed.

Ethical approval was obtained from both the Hong Kong Polytechnic University and the hospitals involved in this study.

Sampling

A total of 26 participants with varicose veins (clinically rated as mild to moderate) who required pressure therapy were recruited in the department of occupational therapy in two regional hospitals in Hong Kong. The inclusion criteria of the participants were (a) age $\geq$ 18 years; (b) a previous record of good compliance in pressure therapy (including Tubigrip, CGs, and ready-made garments, etc.); and (c) recognized by the therapists as having good compliance with pressure therapy. Those who had difficulties in filling in the questionnaires or in attending the follow-up assessment sessions in the study were excluded from the study. All participants were asked to sign a written consent form before engaging in the study.

Pressure garment prescription

For either type of garment, two sets of pressure garments were given to the participants. All participants were given only one type of pressure garment (e.g., a CG or SPMS within a 1-month period). The first type of garment (2 sets) was named as No. 1 and No. 2; and the second type (2 sets) was named as No. 3 and No. 4. The sequence of types of garment was randomized at the very beginning of participant sampling. The two types of garments were sewed to look very similar to ensure effective blindness, while the two sets of the same type of garments were required to be used on alternate days. The instruction for the wearing

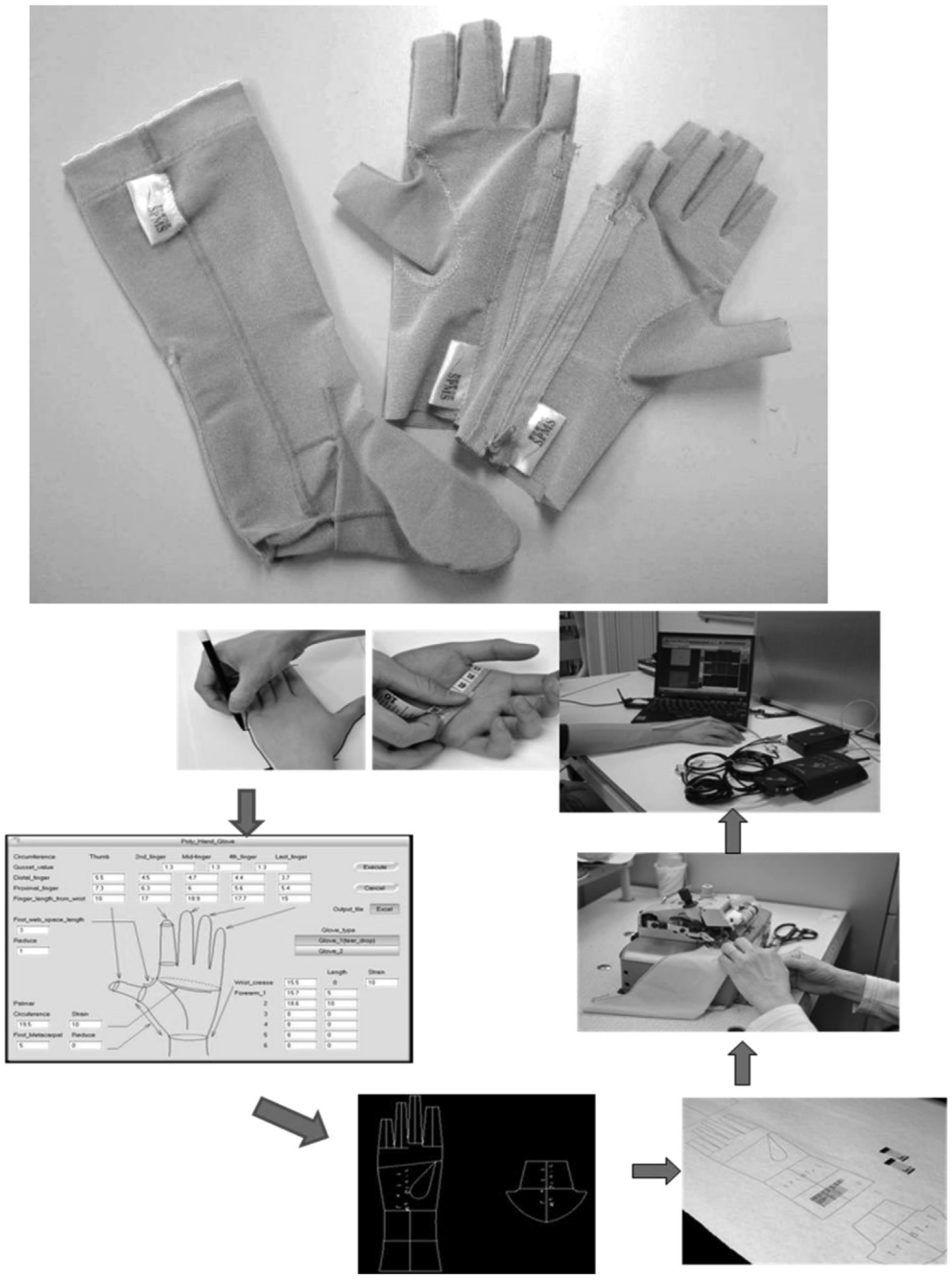

Figure 1 Smart Pressure Monitored Suit sample and its production process.

regime of garments was given, emphasizing the garment set number. The same handling instructions were provided for both types of garments—hand wash and dry in air every day. Participants were asked to keep a diary on garment wear and care in order to monitor their compliance.

Assessment procedures

Objective measurement of interface pressure exerted by pressure garments

The Pliance X system was to measure the interface pressure exerted by the two types of pressure garments, so as to compare their ability to provide pressure and sustain pressure. Fig. S1 shows the Pliance X system used for pressure measurement. Lai and Li-Tsang (2009) have validated the application of the Pliance X system to provide an objective and quantitative measurement of the interface pressure generated by pressure garments.

Patients' feedback on the two types of pressure garments

A questionnaire was adopted to assess the properties of both types of pressure garments. The content of the questionnaire on patient compliance factors was adopted

based on previous studies (Johnson, Greenspan, Gorga, Nagler, & Goodwin, 1994). An expert panel with three experienced occupational therapists, two undergraduates from the Institute of Textile and Clothing, two undergraduates from the School of Nursing, and one pressure garment user was formed for reviewing the validity of this self-administered questionnaire, which is composed of 14 questions.

The properties of the garment mainly contain the following aspects: (a) appearance of the garment; (b) comfort of wear of the garment; (c) joint mobility and movement when wearing the garment; (d) ability to retain the elasticity of the garment; (e) ease of garment handling.

The first six questions in the questionnaire were used to collect the demographic information of the participants. Questions 7 and 8 were about the style of pressure garments and the duration of garment wearing. Questions 9–12 were used to compare the differences of the garment properties between SPMS and CG. Questions 9 and 10 used a five-point scale (where "1" indicated very dissatisfied while "5" represented very satisfied) to assess the satisfaction level of garment users towards the two types of pressure garments. Question 11 aimed to compare the displacement tendency of both types of garments. Question 12 concerned the perceived elasticity of the garments after wearing for 1 month, using a five-point scale, where "1" indicated very low and "5" indicated very high. The final two questions sought opinions from the participants in terms of the overall grading of the SPMS versus the CG.

Therapists' feedback on the SPMS system

A focus-group discussion with the occupational therapists who joined the study was conducted after the completion of the data collection to obtain their feedback.

Statistical analysis

A paired *t* test was used to determine the differences in the interface pressure levels generated by each type of garments before and after wearing for 1 month. An independent *t* test was used to compare the pressure sustainability of the two types of garments. The Mann–Whitney *U* test was used to analyse the items in the self-administered questionnaire for the comparison of the SPMS and the CG ($p < .05$ indicated significant differences). All statistical analyses were performed using SPSS 17.0 (SPSS Inc., Chicago, IL, USA).

Results

Demographic information

A total of 26 participants were recruited to the study. Their mean age was 56.0 ± 9.68 years. A total of 23 were female and the remaining three were male. All the participants received pressure therapy for prevention and management of varicose veins. The types of garments prescribed were mainly socks and pants.

Sustainability of pressure

Significant differences were found in the interface pressure levels generated by both types of pressure garments before and after wearing for 1 month. After 1 month of continuous wearing, the pressure values of both the SPMS and CGs were reduced compared with initial measurements. However, there was a significant difference in terms of the pressure deterioration between the SPMS and CGs ($t = 2.71$, $p = .042$). The SPMS demonstrated a better pressure sustainability than CGs (Fig. 2).

Patients' feedback

From the descriptive statistics, participants gave higher scores for the SPMS than CGs in seven of the 13 items on garment properties. Three of the 13 items received the same score for both garments. The SPMS obtained lower scores than CG in the remaining three items (Table 1). However, from the *t* test score, no significant differences were found between the two types of pressure garments.

For the displacement tendency, 88.5% of the participants (23/26) agreed that the SPMS had satisfactory performance in garment displacement tendency (no displacement or only slight displacement under large movements) compared with that of 73% (19/26) for the CGs (Table 2). Similarly, 27% (7/26) rated unsatisfactory displacement (significant or slight displacement under even small movements) for the CGs, compared with that of 11% (3/26) for the SPMS. There was a significant difference in the percentage of participants who recognized the garment's performance in displacement tendency for SPMS versus CG (chi square = 1.981, $p < .05$).

The satisfaction level rated by patients on the overall efficacy of the SPMS was significantly higher than that of CG (Table 3). The SPMS received a rating of higher satisfaction in overall evaluation than the CGs.

Therapists' feedback

After the completion of data collection from the patients, four occupational therapists involved in this study were

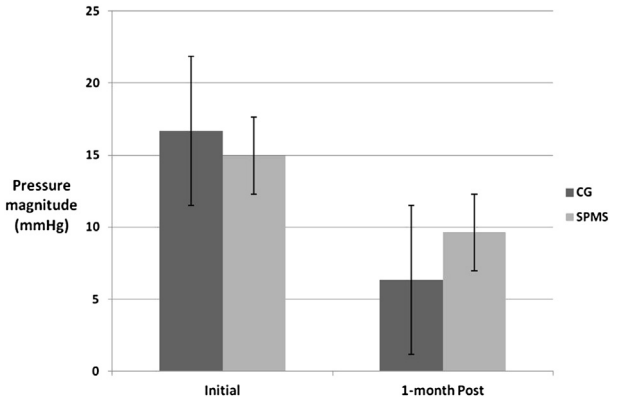

Figure 2 Comparison of pressure sustainability between conventional garments (CGs) and Smart Pressure Monitored Suits (SPMSs).

Table 1 Rating of Satisfaction Level on Garment Properties.

Items	CG	SPMS
Level of itchiness	3.7 ± 0.95	4.1 ± 1.46
Level of softness	4.2 ± 0.98	4.4 ± 0.54
Ease of cleaning	4.6 ± 0.54	4.6 ± 0.79
Ease of drying	4.7 ± 0.49	4.4 ± 0.79
Ease of donning and doffing	4.6 ± 0.55	4.6 ± 0.79
Colour	4.6 ± 0.54	4.7 ± 0.49
Neatness of sewing connection	4.6 ± 0.54	4.1 ± 0.70
Cutting	4.6 ± 0.54	4.6 ± 0.54
Joint mobility	4.4 ± 0.54	4.7 ± 0.49
Smell	4.7 ± 0.76	4.9 ± 0.38
Permeability after sweating	4.3 ± 0.76	4.1 ± 1.07
Tightness after 1-month use	3.4 ± 1.27	4.1 ± 0.69
Elasticity maintenance after washing	3.9 ± 0.90	4.3 ± 0.95

CG = conventional garment; SPMS = Smart Pressure Monitored Suit.

invited to join a focus-group discussion. Subjective feedback on the comparison of the two systems for prescribing pressure garments was collected. The therapists felt that the SPMS system could save their time spent on pattern drafting. Using the computerized system, the patterns can be kept and archived in a better way and be easily transferred to other therapists when needed. The time spent to fabricate the garment patterns was much reduced with the help of the YUKA system. However, they also commented that initially they had to take some time to become familiar with the software system. It also appeared that therapists who are less experienced in drafting garment patterns would prefer to use the YUKA system when compared with those who are more experienced. Most of them agreed that the SPMS had a better appearance and was more accepted by the patients. It was more durable and comfortable. However, the SPMS system will require the installation of the computerized program (YUKA) to a computer and a printer, which should be set up properly at the department. Therapists also commented that they took some time to learn the YUKA software and the methods of measurement, which were different from conventional methods of measurement. In view of the daily clinical workloads, some experienced therapists would prefer using their own ways of fabricating the pressure garment but then, it would require adjustment and trimming by the assistants.

Table 3 Rating of Satisfaction Level on Overall Evaluation of CG and SPMS.

Items	CG	SPMS
Overall efficacy	3.4 ± 0.98*	4.0 ± 0.58*
Overall rating	7.0 ± 2.31	8.3 ± 1.50

*$p < .05$, comparing CG and SPMS.
CG = conventional garment; SPMS = Smart Pressure Monitored Suit.

Discussion

The effectiveness of pressure therapy has largely relied on the optimal pressure dosage prescribed and the sustainability of pressure during the treatment process (Atiyeh, 2007; Cheng et al., 1996; Lai & Li-Tsang, 2009). It is therefore of crucial significance to ensure that enough and effective pressure is exerted onto patients by prescribing appropriate pressure garments. In this study, the initial pressure generated by both CGs and SPMSs was approximately 15 mmHg, which was comparable to the recommended pressure range commonly applied in clinical practice (Linares, Larson, & Willis-Galstaun, 1993; Van den Kerckhove et al., 2005). After wearing for 1 month, the interface pressure of both types of garments had decreased but the SPMS managed to retain the pressure better than the CGs. The SPMS showed a 35% decline of pressure after 1 month of usage, compared with a 62% deterioration of pressure in the CGs, which was almost twice the pressure loss of the SPMS. The SPMS demonstrated a more favourable performance in maintaining the interface pressure than CGs. Our results may also indicate that a higher range of initial pressure could be used to achieve a target range of pressure magnitude when needed, taking into account the deterioration of pressure over time.

Considering the loss of pressure over a month's time, this study also justified a need to check and monitor the pressure on a regular basis rather than a prescription from the counter or from a store. It is important to monitor the pressure deterioration over time so that appropriate adjustments may be made to ensure a consistency of pressure

Table 2 Rating of Satisfaction Level on Garment Displacement in Different Levels of Movements.

Performance		No. of CG	Votes (out of 26) SPMS
Unsatisfactory	Significant displacement under small movements	2	2
	Slight displacement under small movements	5	1
Subtotal		7	3
Satisfactory	Slight displacement under large movements	7	9
	No displacement	12	14
Subtotal		19*	23*

*$p < .05$, comparing CG and SPMS.
CG = conventional garment; SPMS = Smart Pressure Monitored Suit.

generated to control the medical conditions such as varicose vein or scar formation, in accordance with the suggestion of previous research (Lai, Li-Tsang, & Zheng, 2010). This study further confirmed the importance of using the objective pressure measurement method, namely, the Pliance X system, in the prescription of effective pressure therapy intervention (Lai & Li-Tsang, 2009).

Patients' feedback was also more positive on SPMS with a higher scoring on satisfaction of garment properties, including the level of itchiness, softness, colour, joint mobility, smell, tightness, and elasticity maintenance after washing. The level of comfort during wear is a critical determinant for patients' good compliance with the pressure therapy (Cheng et al., 1996; Ripper et al., 2009). Participants in this study felt that the SPMS was more comfortable to wear. They reported less itchy sensation during wearing and that the materials were softer when compared with the CG. The appearance and smell of the SPMS were also more acceptable than those of the CGs.

Allowing normal joint mobilization activities when wearing a pressure garment is also a consideration for patients. Any discomfort and limitation in range of motion may probably lead to discontinuation of the pressure treatment (Ward, Hayes-Lundy, Reddy, Brockway, & Mills, 1992). Participants seemed to rate a higher satisfactory level in joint mobility when wearing the SPMS, compared with that of CG. However, no statistically significant difference was found. Furthermore, elasticity and durability of a garment are the priorities for clients or clinicians when choosing a garment product for pressure therapy (Ng & Hui, 2001; Ripper et al., 2009). Our results showed that the SPMS had higher rating scores for of tightness after 1 month's use and elasticity maintenance after washing, in contrast with CG, although the differences did not achieve statistical significance. As for the garment displacement aspect, the SPMS seemed to have a better ability to restrict displacement during wearing. A significantly higher percentage of participants reported satisfactory displacement tendency during wearing (with little or no displacement) for the SPMS, compared with that for the CGs.

Although there was no significant difference in the subscores of the questionnaire, participants had a preference to wear the SPMS rather than the CGs. The garment users in this study rated a significantly higher score for the SPMS than the CG in terms of the overall efficacy of the pressure garments ($p < .05$). The SPMS appeared to be a more acceptable choice by patients in clinical practice.

Furthermore, using a computerized program, this new standardized system of SPMS would allow the users to adjust the required pressure level and style of the garment pattern conveniently by simply making changes in the pattern plotting program in the computer. Unlike the CGs in which the pattern was measured and drafted by therapists manually, the whole process of fabrication of SPMS was operated more smoothly through a standard method of measurement, and input of data into the YUKA system; the pattern would then be generated through adjustment of percentage strain. Most importantly, it helps to reduce the therapists' time in pattern drafting, fabrication, and fitting of the garments.

The new fabric used in the SPMS system also had improved texture and durability. The computer system also helped better record keeping but the related computer skills required extra training and technical support. Generally speaking, the younger therapists tended to favour usage of the SPMS system.

Limitations of the study

The cross-over study design of the current study may probably induce some carry-over effects on the intervention, especially having no washing period due to ethical concerns. However, the current study mainly focused on objective data on interface pressure of the pressure garments and subjective feedback from patients and therapists. Although the subjective feedback of the same individual on both types of pressure garments was collected, the between-participant variances in subjective feelings were actually eliminated. The potential carry-over effects on the outcome measures were also minimal because the condition of varicose veins was maintained in a stable status without exacerbation throughout this study. The potential bias has further diminished by random allocation of participants to start different treatments first.

However, because the current study only included limited clinical outcomes and the feedback from the therapists was collected qualitatively, the statistical analyses on the clinical effects of the intervention and its cost effectiveness could not be performed. Thus, to understand the clinical efficacy of the new SPMS system, further research would be warranted.

Conclusion

This study aimed to verify the use of a recently developed system (SPMS), to construct pressure garments, and provide pressure-monitored therapeutic treatment. In this study, the SPMS was found to have a better ability to sustain the interface pressure efficacy of the pressure garments; participants had a preference towards wearing the SPMS than CGs. The SPMS also had the advantage of providing a standardized procedure to generate the pattern for garment fabrication using a computerized program.

To summarize, this standardized system using a SPMS to provide pressure intervention, together with careful pressure monitoring appeared to be a suitable option for use in clinical practice. With proper training on the system usage and further studies to prove the clinical effectiveness, this new method of pressure therapy prescription could possibly facilitate the therapists' intervention in terms of both time and efficiency when in the future there may be fewer therapists skilled in tailoring and pattern drafting.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.hkjot.2013.11.002.

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